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Attorney Docket No. 24020-X

BOX PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Batsheva KEREM

Serial No. 09/871,809

Filed: June 4, 2001

For: CONTROL OF GENE EXPRESSION

Technology Center 2600

### TRANSMITTAL LETTER

The Commissioner for Patents Washington, D.C. 20231

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- (1)Transmittal Letter;
- Supplemental Information Disclosure Statement Transmittal (2) Letter;
- Supplemental Information Disclosure Statement; and (3)
- PTO Form 1449 with 12 references. (4)

Respectfully submitted, NATH & ASSOCIATES PLLC

Bv:

Gary M. Nath Registration No. 26,965 Customer No. 20529

Date: September 4, 2001 NATH & ASSOCIATES PLLC 1030 15<sup>TH</sup> Street, NW - 6<sup>th</sup> Floor Washington, D.C. 20005

GMN/JKH:dd:IDS.trans

Attorney Docket No. 24020-X

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Batsheva KEREM

Serial No. 09/871,809

Filed: June 4, 2001

For: CONTROL OF GENE EXPRESSION

Attorney: GMN/JKH

Group Art Unit: 2684

Examiner: unknown

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner of Patents Washington, D.C. 20231

#### SIR:

2 1 2001

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. §1.97-1.98. Please note the following particulars:

[NOTE: One only of items a, b, c, and d must be checked.]

- [X] a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. §1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.
- [ ] b. The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. §1.113, or a notice of allowance under 37 C.F.R. §1.311.

The enclosed statement is accompanied by [sheck one].

- [] i. a certification in part (e) below as specified in 37 C.F.R. §1.97(e), or
- [] ii.a check in the amount of \$240.00 required by 37 C.F.R. §1.17(p).
- [ ] c. The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. §1.113, or a notice of allowance under 37 C.F.R. §1.311, but before payment of the issue fee.

PETITION: It is requested that the information being submitted be considered. [NOTE: If box (c) is checked, the following two boxes must be checked.]

- PETITION FEE: A check for \$130.00 required by 37 CFR §1.17(i)(1), is enclosed.
- [ ] CERTIFICATION is attended to in box (e) below.

- The enclosed statement is being filed pursuant to ر] d. 37 C.F.R. §1.97(i), for placement in the file.
- Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]
- ſ I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

or

[ ] I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

or

- ] Appropriate certification is attached.
- [ X ] f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112. A duplicate of this sheet is enclosed.

Respectfully submitted,

NATH & ASSOCIATES, PLLC

Date: September 21, 2001

By:

Gary (M

Registration No. 26,965

Customer No. 20529

NATH & ASSOCIATES, PLLC

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BOX PATENT

Attorney Docket No. 24020-X

# THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Group Art Unit: 2684

Batsheva KEREM

Serial No. 09/871,809 Filed: June 4, 2001

For: CONTROL OF GENE EXPRESSION

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents Washington, D.C. 20231

Sir:

Pursuant to Applicant's duty of disclosure under 37 C.F.R. \$\$1.56 and 1.97-1.99, the documents listed on the attached Form PTO-1449 are being brought to the attention of the Examiner in charge of the above-identified application. No fee is required for this submission because it is submitted before the mailing date of a first Office Action on the merits.

Copies of the documents are attached herewith with a completed Form PTO-1449. The Examiner is respectfully requested to the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449

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Docket No. 24020X

with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,

NATH & ASSOCIATES

Date: September  $\mathcal{J}$  , 2001

Gary M. Nath

Registration No. 26,965

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(GMN/jkh:IDS)

Page of 2 Atty Docket Serial No. 24020-X 09/871,809 FORM PTO-1449 Applicant KEREM et al. ION DISCLOSURE CITATION Filing Date Group Art Unit June 4, 2001 2684 U.S. PATENT DOCUMENTS Examiner Document Issue Sub-Filing Name Class Initial Number Date Class Date AΑ AΒ ACAD ΑE AF AG AΗ ΑI AιT AKFOREIGN PATENT DOCUMENTS Document Sub-Trans-Date Country Class Number Class lation ALΑM AN ΑO AΡ OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Mayeda, A. et al., "Modulation of Exon Skipping and Inclusion by Heterogeneous Nuclear Ribonucleoprotein A1 and Pre-mRNA Splicing Factor SF2/ASF", Molecular and Cellular Biology, 13:5 2993-3001 AR (1993). Hanamura, A. et al., " Regulated tissue-specific expression of antagonistic pre-mRNA splicing factors", RNA, 4:430-444 (1998). AS Nordqvist,K., et al., "Human Adenovirus Encodes Two Proteins Which Have Opposite Effects on Accumulation of Alternativley Sliced mRNAs", Molecular and Cellular Biology, 14:1 437-445 ΑT (1994).Examiner Date Considered Initial if reference considered, whether or not citation is in conformance with MPEP  $\S$  609.

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

of 2

M PTO-1449 DISCLOSURE CITATION

Atty Docket 24020-X

Serial No.

09/871,809

Applicant

KEREM et al.

Filing Date June 4, 2001

Group Art Unit 2684

### U.S. PATENT DOCUMENTS

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	BA		Augarten, A. et al., "Mild cystic fibrosis and normal or borderline sweat test in patients with the 3849+10 kb C→T
<del></del>		<del>                                     </del>	mutation, The Lancet, 342:25-26 (1993).
	ВВ		Chiba-Falek,O. et al., "The Molecular Basis of Disease Variability among Cystic Fibrosis Patients Carrying the 3849+10 kb C→T Mutation", <i>Genomics</i> , 53:276-283 (1998).
	BC		Highsmith, W. et al., "A Novel Mutation in the Cystic Fibrosis Gene in Patients with Pulmonary Disease but Normal Sweat Chloride Concentrations", The New England Journal of Medicine, 331:15 974-980 (1994).
	BD		Kerem, E. et al., "A Cystic Fibrosis Transmembrane Conductance Regulator Splice Variant with Partial Penetrance Associated with Variable Cystic Fibrosis Presentations", Am. J. Respir. Crit. Care Med., 155:1914-1920 (1997).
	BE		Rave-Harel, N. et al., "The Molecular Basis of Partial Penetrance of Splicing Mutations in Cystic Fibrosis", Am. J. Hum. Genet., 60:87-94, (1997).
	BF		Chu, C. et al., "Genetic basis of variable exon 9 skipping in cystic fibrosis transmembrane conductance regulator mRNA", Nature Genetics, 3:151-156 (1993).
	BG		Biamonti,G. et al., "Isolation of an Active Gene Encoding Human hnRNP Protein A1", <i>J. Mol. Biol.</i> , 207:491-503 (1989).
	вн		Cáceres, J. et al., "Regulation of Alternative Splicing in Vivo by Overexpression of Antagonistic Splicing Factors", <i>Science</i> , 265:1706-1709 (1994).
	ві		Yang, X. et al., "The A1 and A1B proteins of Heterogeneous Nuclear ribonucleoparticles modulate 5' splice site selection in vivo", Proc. Natl. Acad. Sci. USA, 91:6924-6928 (1994).
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Evaminer			

Date Considered

Initial if reference considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. EXAMINER: